ReadMe for
LOINC Mapping Spreadsheet

Version 1.0 (Final)

Prepared by the CDISC Lab Team

Notes to Readers

This document contains mappings between LOINC in laboratory-related classes to CDISC variables and controlled terminology values in the CDISC LB domain.

Revision History

Date	Version
2020-08-07	1.0 Final

1 Introduction

The US Food and Drug Administration (FDA) will require the submission of LOINC (Logical Observation Identifiers Names and Codes) codes within clinical LB domain data sets in new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs), and for certain investigational new drugs (INDs) for studies that start after March 15, 2020 (March 15, 2021, for certain INDs). The LOINC requirement is not applicable to SEND LB datasets. The LOINC Working Group (composed of FDA, US National Institutes of Health (NIH), Clinical Data Interchange Standards Consortium (CDISC), and Regenstrief Institute) produced a recommendations document for the submission of LOINC codes in regulatory applications to the FDA (https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm586363.pdf).

The recommendations document calls for the development of a mapping file to map the most commonly submitted LOINCs in clinical research to the associated CDISC terminology components associated with each LOINC part. Please refer to the recommendations document for an explanation of the implementation of this requirement. Additional information about the submission of LOINC codes to the FDA can be found in the *Study Data Technical Conformance Guide*, Section 6.7.1.1 (https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources).

2 Description and Methodology of Mapping

The following versions of related standards documents were used in the development of this example mapping file:

Standards Document	Version Identifier
CDISC SDTM Terminology	2020-06-26
SDTM	Version 1.7
SDTM Implementation Guide	Version 3.3
LOINC	Version 2.68 (Release Date: 2020-06-17)

The mapping file is composed of LOINCs from the 2005 CDISC-LOINC mapping project, the LOINC Top 2000 SI, and the LOINC Top 2000 US, as well as CDISC LB domain datasets that were submitted to FDA during the years 2014-2016. The mapping includes more than 1,400 LOINCs across the Chemistry, Hematology, Coagulation, Toxicology, Urinalysis, Serology, and Miscellaneous categories. The LOINC mapping will not include LOINCs relevant to microbiology, pathology, genomics, vital signs, fetal/neonatal screening, or administrative questions, as these are modeled in other Standard Data Tabulation Model (SDTM) domains. Uncommon allergens also will not be included, as their submission in a dataset would be rare. The mapping does not include deprecated or discouraged codes. The final published example mapping document references a single version of CDISC Controlled Terminology and a single version of LOINC; it will not be maintained or up-versioned over time by CDISC.

The LOINC is a pre-coordinated code that contains 6 parts or aspects, not all of which may be specified for each LOINC: Component, Property, Time, System, Scale, and Method (see https://loinc.org/). The CDISC lab model contains many more variables to represent a lab test and is considered a post-coordinated model. In other words, one LOINC code will map to many CDISC controlled terms within and across multiple variables/codelists relevant to the LB domain. Because the LOINC contains only 6 parts, some additional aspects of a lab test may have been integrated into a LOINC part that is inconsistent with other values within that part. Therefore, additional variables and non-standard variables (NSVs) are used on the CDISC side of this mapping to ensure consistency in alignment to the CDISC model as well as data fitness.

In general, the LOINC Component maps to LBTEST and LBTESTCD but may also map to LBPOS, LBFAST, or LBTPT; the LOINC Property maps to the NSV --RESTYP (Result Type); the LOINC Time aspect may map to either the NSV --PTFL (Point in Time Flag) or --PDUR (Planned Duration); the LOINC System maps to LBSPEC or LBLOC; and the LOINC Method maps to the CDISC variables LBMETHOD or LBANMETH, or the NSVs --TSTOPO (Test Operational Objective), --LLOD (Lower Limit of Detection), --TSTCND (Test Condition), or --MTHSEN (Method Sensitivity; see Table 1). These aforementioned NSVs will be integrated into the SDTM as standard variables.

Table 1. LOINC Components and CDISC Equivalents[a]

LOINC: 6 Parts in 1 Code	LOINC: Part Description	LOINC: Example (13986-5)	CDISC: Maps to Multiple Variables
Component	Analyte: The substance or entity being measured or observed. May include other information.	Albumin/Protein.total	LBTEST; LBTESTCD; --POS; --FAST; --TPT
Property	The dimension of the analyte observation value	MFR (Mass Fraction)	--RSLTYP
Time	The point in time or interval of time over which an observation or assessment was made	24H	--PTFL; --PDUR
System	The specimen or entity upon which the observation was made	Urine	--SPEC; --LOC
Scale	The scale of the result value: How the observation value is expressed (e.g., quantitative, ordinal, nominal)	Quantitation	--RSLSCL
Method	Assay method: High-level description for how the measurement or assessment was performed	Electrophoresis	--METHOD; --ANMETH; --TSTOPO; --LLOD; --TSTCND; --MTHSEN

[a]One LOINC code maps to many CDISC concepts. One LOINC part may map to more than 1 CDISC variable. Variables in green are published CDISC variables and variables in purple are NSVs.

Any unique combination of values in the CDISC variables must map to 1 and only 1 LOINC code. Conversely, multiple CDISC combinations of terms may map to a single LOINC code, especially when a LOINC concept contains multi-valued (e.g. Specimen of SER/PLAS), unspecified, or NULL (e.g. Methodless LOINC Codes) parts. If the LOINC code in the mapping had a part concept with finer granularity than published CDISC terminology, CDISC developed new terminology to match the LOINC level of detail.

The use of (***) in the LBSPEC field in Column M indicates a LOINC system of XXX. Lab vendors have interpreted this to mean that the LOINC can be used for those tests where the specimen type is known but a specimen-specific LOINC code does not exist for that specimen type. The use of (***) in the LBMETHOD field in Column O indicates a blank Method part in LOINC. Lab vendors have interpreted this to mean that the LOINC can be used for those tests wherein the METHOD is not known, or for those tests where the method is known but a Method-specific LOINC code does not exist.

Column Q of the mapping includes an example unit of measure using a CDISC Submission Value appropriate to the LOINC property part. This example unit is not exclusive and other property-appropriate units of measure may also be used with that LOINC. In order to appropriately implement LOINC codes containing the following LOINC properties: Aper, Imp, LsCnc, MoM, Morph, Num, Prid, PrThr, RDen, Score, Type, and Visc, the unit of measure associated with the submitted result must be null; therefore, (Must be null) in the LBORRESU column indicates that a unit of measure is not appropriate.

There are a few cases in which the LOINC component name is at a different level of granularity than the CDISC LBTEST and TESTCD name:

1. In the case of Excretion Rate-type terms, the LOINC component just specifies the analyte generically, i.e., <<analyte name>>, while making its test type explicit via the property part value. Conversely, the CDISC LBTEST value is <<analyte name>> Excretion Rate, as CDISC has chosen to make excretion rate -ype terms explicit via the Test Name because the unit type is very different (e.g., Albumin for LOINC 14956-7 vs LOINC 2862-1).
2. In the case of Partial Pressure-type terms, the LOINC component just specifies the analyte generically, i.e., <<analyte name>>, while making its test type explicit via the property part value. Conversely, the CDISC LBTEST value is Partial Pressure <<analyte name>>, as CDISC has chosen to make partial pressure-type terms explicit via the Test Name because the unit type is very different (e.g., Carbon Dioxide for LOINC 11557-6 vs LOINC 20565-8).

3 CDISC Controlled Terminology and NCI C-codes

Columns of NCI C-codes associated with published CDISC Controlled Terminology submission values were added to the example mapping document to support the LBTEST/TESTCD, LBSPEC, LBMETHOD, LBORRESU, LBANMETH, LBPOS, LBLOC, and LBFAST variable columns. Several of the proposed SUPPQUAL NSVs in the mapping will be controlled with CDISC Controlled Terminology in the future. These include --LBPTFL, --TSTOPO, --RESTYP, --RSLSCL, and --MTHSEN. This example mapping document will be published before much of the terminology associated with the SUPPQUAL NSVs is published. NCI C-codes associated with the SUPPQUAL NSV columns were not added at the time of publication, and it cannot be guaranteed that the proposed CDISC submission values in the published mapping will be the same as the final published submission values.

4 Mapping Use Considerations

This mapping is intended to show examples of LOINC code mappings to CDISC variables and terminology, to aid researcher adoption of the FDA requirement. Sponsors should work closely with their lab vendors to implement the FDA requirement. Because lab vendors are expected to provide the LOINCs, lab and device vendors are expected to gain the most from this mapping. Lab vendors should provide, at minimum, the LOINCs included within this mapping, if available. This mapping is not intended to be used for automated creation or validation of LOINC to CDISC LB mappings. For more information about FDA's expectations and requirements, please reference the previously cited recommendations and *Technical Conformance Guide*.

5 Copyright

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